



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

February 11, 2021

Thomas Lingelbach
Chief Executive Officer
Valneva SE
6 rue Alain Bombard
44800 Saint-Herblain, France

Re: Valneva SE
Draft Registration Statement on Form F-1
Submitted January 15, 2021
CIK No. 0001836564

Dear Mr. Lingelbach:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1

Cover Page

1. We note that you intend to disclose the last reported sale price of your ordinary shares on Euronext Paris on the cover page, and your disclosure that the final offering price will be determined through negotiations with the underwriters by reference to the prevailing market prices of your ordinary shares on Euronext Paris after taking into account market conditions and other factors. Please confirm that the U.S. IPO price will be substantially similar to the Euronext Paris trading price, converted to U.S. dollars at the most recent exchange rate. If you intend to price the securities based on the Euronext Paris market price, you may also disclose a percentage range based on that price (for example, 10% of the home market price) within which you intend to price the securities. Alternatively, if

you expect that the U.S. IPO price will not be substantially similar to the Euronext Paris trading price, please disclose on the cover page a bona fide price range of the offered securities. See Item 501(b)(3) of Regulation S-K.

Prospectus Summary

Overview, page 1

2. Please revise the third paragraph in this section to disclose that you currently do not have a commercial license for the specific virus strain that you use in VLA2001 and are in the process of negotiating a license agreement with the World Health Organization.

Our Portfolio and Pipeline, page 2

3. We note that you have included your parvovirus and norovirus programs in your pipeline table, which appear to be in the discovery phase. Given the early-stage development of these programs, please explain why each program is sufficiently material to your business to warrant inclusion in your pipeline table.
4. Please revise the narrative description regarding VLA15 on page 3 to disclose that Pfizer will lead late-stage development of VLA15 and will have sole control over its commercialization pursuant to your collaboration agreement with Pfizer.
5. Please revise to provide balance and context to your references to "positive" initial results, "positive" data, "encouraging" preclinical results, a "promising" Phase 1 dataset and "promising" clinical data from your trials both here and in the Business section. In this regard, we note your risk factor on page 20 concerning the limitations of pre-clinical and earlier clinical data. Please also clarify, if true, that the data you present is not statistically significant.

Implications of Being an Emerging Growth Company, page 8

6. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Material Weaknesses, page 117

7. You disclose that you have begun to develop a remediation plan to address certain material weaknesses and strengthen your controls in those areas. Please revise your filing to state the estimated time period to develop and execute your remediation plan.

Business

Phase 1 Clinical Trial and Results, page 130

8. We note your statement on page 130 that VLA15 demonstrated a "favorable" safety profile. Please revise this statement to remove implication that your product candidate is safe, as this determination is solely within the authority of the FDA.

Material Agreements

Department of Defense Contracts, page 154

9. Please file the agreements with the U.S. Department of Defense as exhibits to the registration statement, or, in the alternative, please tell us why you believe that you are not required to file the agreements. See Item 601(b)(10) of Regulation S-K.

UK Supply Agreement, page 155

10. Please revise to disclose the aggregate amounts received to date under the agreement.

Intellectual Property

Patents and Patent Applications, page 159

11. We note your disclosure on page 42 that two of your patents have been limited in scope in opposition proceedings in Europe and the patents could ultimately be revoked. It appears that you only discuss one of the two patents in the IXIARO section on page 160. Please revise to identify the other patent or clarify whether both patents pertain to IXIARO. Please also revise to disclose if you expect the potential revocation of these patents to have any material impact on your plans for further commercialization of IXIARO, your development plans for your product candidates, if applicable, your patent portfolio and your business.

Principal Shareholders, page 203

12. Please revise your disclosure to identify the natural person or persons who have voting and investment control of the shares held by each of your 5% shareholders.

Description of American Depositary Shares

Governing Law/Waiver of Jury Trial, page 242

13. We note your disclosure that the deposit agreement requires ADS holders to waive the right to a jury trial of any claim they may have against you or the depositary arising out of or relating to your ordinary shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws. Please add a risk factor to the prospectus describing this provision, the risks of the provision or other impacts on shareholders, any uncertainty about enforceability, the impact on claims arising under other laws, and whether or not the provision applies to purchasers in secondary transactions.

Thomas Lingelbach
Valneva SE
February 11, 2021
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You may contact Tracey McKoy at 202-551-3772 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmento at 202-551-3798 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Marc Recht